



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION III
1650 Arch Street
Philadelphia, Pennsylvania 19103-2029

JAN 11 2016

Mr. Reg Tanner
Director, Safety and Environment
Merck Sharp & Dohme Corp.
2778 South East Side Highway
Elkton, Virginia 22827

Re: Merck Sharp & Dohme Corp.
EPA Docket No. CAA-III-16-0001

Dear Mr. Tanner:

From May 11-14, 2015, EPA conducted an air compliance evaluation of the Merck Sharp & Dohme Corp. (Merck) pharmaceutical manufacturing facility, located at 2778 South East Side Highway, Elkton, Virginia 22827 (the Facility). The May 2015 inspection is part of an on-going Environmental Protection Agency (EPA) Region III Clean Air Act (CAA) compliance investigation by EPA Region III's Air Protection Division. This is a Notice of Noncompliance and Show Cause Notification relating to the above described on-going CAA compliance investigation.

Based upon EPA's review of information relating to the Facility's CAA compliance, EPA believes that the Facility failed to comply with certain federally enforceable requirements applicable to the Facility. A summary of alleged CAA non-compliance is enclosed herein. See Enclosure A (General Summary of Allegations of Noncompliance with the Clean Air Act). EPA is interested in discussing the areas of non-compliance summarized in Enclosure A with Merck representatives.

Certain companies may be required to disclose to the Securities and Exchange Commission (SEC) the existence of certain pending or known to be contemplated environmental legal proceedings (administrative or judicial) arising under federal, state or local environmental laws. Please see the attached "Notice of Securities and Exchange Commission Registrants' Duty to Disclose Environmental Legal Proceedings" for more information about this requirement and to aid you in determining whether your company may be subject to the same. In addition, EPA is enclosing an Information Sheet entitled "U.S. EPA Small Business Resources," (EPA 300-F-99-004, September 1999), which identifies a variety of compliance assistance and other tools available to assist small businesses in complying with federal and state environmental laws.

**REQUEST FOR INFORMATION
&
OPPORTUNITY TO CONFER**

In order to initiate discussions regarding this matter, EPA is requesting an opportunity to confer with you and other representatives of the Facility. The purposes of such discussion would be to: 1) discuss any additional information that Merck representatives may have demonstrating that EPA's summary of alleged violations set forth in Enclosure A is incorrect and 2) provide any additional information relevant to EPA's determination of whether EPA Region III should consider any potential enforcement action relating to the summary of allegations set forth in Enclosure A.

In order to expedite discussion of this matter, by this letter, EPA is requesting a timely response to this letter and submission of any additional information demonstrating that EPA's summary of alleged violations set forth in Enclosure A is not correct. Therefore, EPA is requesting that Merck representatives respond to this letter within fifteen (15) business days of your receipt of this letter. If Merck representatives do not respond within fifteen (15) business days of receipt of this letter, the Agency may determine an appropriate enforcement response without further prior notice to you.

Please send any and all information responsive to the above request, and direct any request for a settlement conference, to the attention of:

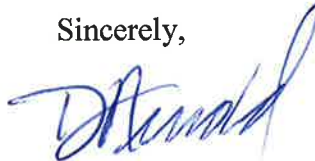
Mr. Bruce Augustine
Environmental Scientist
Air Protection Division (3AP20)
U.S. EPA, Region III
1650 Arch Street
Philadelphia, PA 19103-2029
Phone: 215-814-2131

We look forward to discussing this matter further with Merck representatives. If you have any questions regarding anything in this letter, please contact Bruce Augustine at your earliest convenience at (215) 814-2131 or at augustine.bruce@epa.gov.



Alternatively, in the event that Merck is represented by legal counsel, such legal counsel may contact Ms. Donna Mastro, Air Branch Chief in EPA Region III's Office of Regional Counsel at (215) 814-2777 or at mastro.donna@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "D. Arnold", is positioned above the printed name.

David L. Arnold, Acting Director
Air Protection Division

Enclosures



Enclosure A

1. The Merck Stonewall Plant is a major source of hazardous air pollutant (HAP) emissions.¹ Based on information provided during the inspection, Merck has been a major source of HAP since at least 2010. Since the facility is a major source of HAP emissions and it is a pharmaceutical production facility, it is subject to the requirements of 40 C.F.R. Subpart GGG. Merck has not complied with the notification, recordkeeping, and reporting requirements of MACT Subpart GGG since at least 2010 (40 C.F.R. §§ 63.1250-1261).

2. Section IV.B.8 of Title V permit No. VRO80524 requires that a first attempt at repair shall be made no more than 5 in-service calendar days after a leak is detected. Based on information provided in Merck's LDAR database, Merck failed to perform a first attempt at repair on three (3) connectors and one (1) pump between January 2010 and April 2015.

3. Section IV.B.8 of Title V permit No. VRO80524 requires that a final repair shall be made no more than 15 in-service calendar days after a leak is detected. Based on information provided in Merck's LDAR database, Merck failed to perform a final repair on 11 valves, 27 connectors, 2 pressure relief devices, 1 instrumentation system, and 2 pumps within 15 days of detecting a leak between January 2010 and April 2015.

¹ 42 U.S.C. § 7412 (CAA §112) defines a major source as a facility with the potential to emit total HAP >25 ton/yr or 10 ton/yr of a single HAP.





U.S. EPA Small Business Resources Information Sheet

The United States Environmental Protection Agency provides an array of resources to help small businesses understand and comply with federal and state environmental laws. In addition to helping small businesses understand their environmental obligations and improve compliance, these resources will also help such businesses find cost-effective ways to comply through pollution prevention techniques and innovative technologies.

Small Business Programs

www.epa.gov/smallbusiness
EPA's Office of Small Business Programs (OSBP) advocates and fosters opportunities for direct and indirect partnerships, contracts, and sub-agreements for small businesses and socio-economically disadvantaged businesses.

EPA's Asbestos Small Business Ombudsman

www.epa.gov/sbo or 1-800-368-5888
The EPA Asbestos and Small Business Ombudsman (ASBO) serves as a conduit for small businesses to access EPA and facilitates communications between the small business community and the Agency.

EPA's Compliance Assistance Homepage

www2.epa.gov/compliance
This page is a gateway industry and statute-specific environmental resources, from extensive web-based information to hotlines and compliance assistance specialists.

EPA's Compliance Assistance Centers

www.assistancecenters.net
EPA's Compliance Assistance Centers provide information targeted to industries with many small businesses. They were developed in partnership with industry, universities and other federal and state agencies.

Agriculture

www.epa.gov/agriculture/

Automotive Recycling

www.ecarcenter.org

Automotive Service and Repair

ccar-greenlink.org/ or 1-888-GRN-LINK

Chemical Manufacturing

www.chemalliance.org

Construction

www.cicacenter.org or 1-734-995-4911

Education

www.campuserc.org

Food Processing

www.fpeac.org

Healthcare

www.hercenter.org

Local Government

www.lgean.org

Metal Finishing

www.nmfrc.org

Paints and Coatings

www.paintcenter.org

Printing

www.pneac.org

Ports

www.portcompliance.org

Transportation

www.tercenter.org

U.S. Border Compliance and Import/Export Issues

www.bordercenter.org

EPA Hotlines, Helplines and Clearinghouses

www2.epa.gov/home/epa-hotlines

EPA sponsors many free hotlines and clearinghouses that provide convenient assistance regarding environmental requirements. Some examples are:

Clean Air Technology Center (CATC) Info-line

www.epa.gov/ttn/catc or 1-919-541-0800

Superfund, TRI, EPCRA, RMP and Oil Information Center

www.epa.gov/superfund/contacts/infocenter/index.htm or 1-800-424-9346

EPA Imported Vehicles and Engines Public Helpline

www.epa.gov/otaq/imports or 734-214-4100

National Pesticide Information Center

www.npic.orst.edu/ or 1-800-858-7378

National Response Center

Hotline to report oil and hazardous substance spills - www.nrc.uscg.mil or 1-800-424-8802

Pollution Prevention Information Clearinghouse (PPIC) -

www.epa.gov/opptintr/ppic or 1-202-566-0799

Safe Drinking Water Hotline -

www.epa.gov/drink/hotline/index.cfm or 1-800-426-4791

Stratospheric Ozone Protection Hotline

www.epa.gov/ozone/comments.htm or 1-800-296-1996

Toxic Substances Control Act (TSCA) Hotline

tsc hotline@epa.gov or 1-202-554-1404

Small Entity Compliance Guides

<http://www.epa.gov/sbrefa/compliance-guides.html>

EPA publishes a Small Entity Compliance Guide (SECG) for every rule for which the Agency has prepared a final regulatory flexibility analysis, in accordance with Section 604 of the Regulatory Flexibility Act (RFA).

Regional Small Business Liaisons

<http://www.epa.gov/sbo/rsbl.htm>

The U.S. Environmental Protection Agency (EPA) Regional Small Business Liaison (RSBL) is the primary regional contact and often the expert on small business assistance, advocacy, and outreach. The RSBL is the regional voice for the EPA Asbestos and Small Business Ombudsman (ASBO).

State Resource Locators

www.envcap.org/statetools

The Locators provide state-specific contacts, regulations and resources covering the major environmental laws.

State Small Business Environmental Assistance Programs (SBEAPs)

www.epa.gov/sbo/507program.htm

State SBEAPs help small businesses and assistance providers understand environmental requirements and sustainable business practices through workshops, trainings and site visits.

EPA's Tribal Portal

www.epa.gov/tribalportal/

The Portal provides access to information on environmental issues, laws, and resources related to federally recognized tribes.

EPA Compliance Incentives

EPA provides incentives for environmental compliance. By participating in compliance assistance programs or voluntarily disclosing and promptly correcting violations before an enforcement action has been initiated, businesses may be eligible for penalty waivers or reductions. EPA has two such policies that may apply to small businesses:

EPA's Small Business Compliance Policy

www2.epa.gov/enforcement/small-businesses-and-enforcement

This Policy offers small businesses special incentives to come into compliance voluntarily.

EPA's Audit Policy

www2.epa.gov/compliance/epas-audit-policy

The Policy provides incentives to all businesses that voluntarily discover, promptly disclose and expeditiously correct their noncompliance.

Commenting on Federal Enforcement Actions and Compliance Activities

The Small Business Regulatory Enforcement Fairness Act (SBREFA) established a SBREFA Ombudsman and 10 Regional Fairness Boards to receive comments from small businesses about federal agency enforcement actions. If you believe that you fall within the Small Business Administration's definition of a small business (based on your North American Industry Classification System designation, number of employees or annual receipts, as defined at 13 C.F.R. 121.201; in most cases, this means a business with 500 or fewer employees), and wish to comment on federal enforcement and compliance activities, call the SBREFA Ombudsman's toll-free number at 1-888-REG-FAIR (1-888-734-3247).

Every small business that is the subject of an enforcement or compliance action is entitled to comment on the Agency's actions without fear of retaliation. EPA employees are prohibited from using enforcement or any other means of retaliation against any member of the regulated community in response to comments made under SBREFA.

Your Duty to Comply

If you receive compliance assistance or submit a comment to the SBREFA Ombudsman or Regional Fairness Boards, you still have the duty to comply with the law, including providing timely responses to EPA information requests, administrative or civil complaints, other enforcement actions or communications. The assistance information and comment processes do not give you any new rights or defenses in any enforcement action. These processes also do not affect EPA's obligation to protect public health or the environment under any of the environmental statutes it enforces, including the right to take emergency remedial or emergency response actions when appropriate. Those decisions will be based on the facts in each situation. The SBREFA Ombudsman and Fairness Boards do not participate in resolving EPA's enforcement actions. Also, remember that to preserve your rights, you need to comply with all rules governing the enforcement process.

EPA is disseminating this information to you without making a determination that your business or organization is a small business as defined by Section 222 of the Small Business Regulatory Enforcement Fairness Act or related provisions.

NOTICE OF SECURITIES AND EXCHANGE COMMISSION REGISTRANTS' DUTY TO DISCLOSE ENVIRONMENTAL LEGAL PROCEEDINGS

Securities and Exchange Commission regulations require companies registered with the SEC (e.g., publicly traded companies) to disclose, on at least a quarterly basis, the existence of certain administrative or judicial proceedings taken against them arising under Federal, State or local provisions that have the primary purpose of protecting the environment. Instruction 5 to Item 103 of the SEC's Regulation S-K (17 CFR 229.103) requires disclosure of these environmental legal proceedings. For those SEC registrants that use the SEC's "small business issuer" reporting system, Instructions 1-4 to Item 103 of the SEC's Regulation S-B (17 C FR 22 8.103) requires disclosure of these environmental legal proceedings.

If you are an SEC registrant, you have a duty to disclose the existence of pending or known to be contemplated environmental legal proceedings that meet any of the following criteria (17 CFR 229.103)(5)(A)-(C)):

- A. Such proceeding is material to the business or financial condition of the registrant;
- B. Such proceeding involves primarily a claim for damages, or involves potential monetary sanctions, capital expenditures, deferred charges or charges to income and the amount involved, exclusive of interest and costs, exceeds 10 percent of the current assets of the registrant and its subsidiaries on a consolidated basis; or
- C. A governmental authority is a party to such proceeding and such proceeding involves potential monetary sanctions, unless the registrant reasonably believes that such proceeding will result in no monetary sanctions, or in monetary sanctions, exclusive of interest and costs, of less than \$100,000; provided, however, that such proceedings which are similar in nature may be grouped and described generically.

Specific information regarding the environmental legal proceedings that must be disclosed is set forth in Item 103 of Regulation S-K or, for registrants using the "small business issuer" reporting system, Item 103(a)-(b) of Regulation S-B. If disclosure is required, it must briefly describe the proceeding, "including the name of the court or agency in which the proceedings are pending, the date instituted, the principal parties thereto, a description of the factual basis alleged to underlie the proceedings and the relief sought."

You have been identified as a party to an environmental legal proceeding to which the United States government is, or was, a party. If you are an SEC registrant, this environmental legal proceeding may trigger, or may already have triggered, the disclosure obligation under the SEC regulations described above.

This notice is being provided to inform you of SEC registrants' duty to disclose any relevant environmental legal proceedings to the SEC. This notice does not create, modify or interpret any existing legal obligations, it is not intended to be an exhaustive description of the legally applicable requirements and it is not a substitute for regulations published in the Code of Federal Regulations. This notice has been issued to you for information purposes only. No determination of the applicability of this reporting requirement to your company has been made by any governmental entity. You should seek competent counsel in determining the applicability of these and other SEC requirements to the environmental legal proceeding at issue, as well as any other proceedings known to be contemplated by governmental authorities.

If you have any questions about the SEC's environmental disclosure requirements, please contact the SEC Office of the Special Senior Counsel for Disclosure Operations at (202) 551-3115.

[Code of Federal Regulations]
[Title 17, Volume 2, Parts 200 to 239]
[Revised as of April 1, 1999]
From the U.S. Government Printing Office via GPO Access
[CITE: 17CFR229.103]

[Page 349]

TITLE 17--COMMODITY AND SECURITIES EXCHANGES

CHAPTER II--SECURITIES AND EXCHANGE COMMISSION

PART 229--STANDARD INSTRUCTIONS FOR FILING FORMS UNDER SECURITIES ACT OF 1933,
SECURITIES EXCHANGE ACT OF 1934 AND ENERGY POLICY AND CONSERVATION ACT OF 1975--
REGULATION S-K--Table of Contents

Subpart 229.100--Business

Sec. 229.103 (Item 103) Legal proceedings.

Describe briefly any material pending legal proceedings, other than ordinary routine litigation incidental to the business, to which the registrant or any of its subsidiaries is a party or of which any of their property is the subject. Include the name of the court or agency in which the proceedings are pending, the date instituted, the principal parties thereto, a description of the factual basis alleged to underlie the proceeding and the relief sought. Include similar information as to any such proceedings known to be contemplated by governmental authorities.

Instructions to Item 103:

1. If the business ordinarily results in actions for negligence or other claims, no such action or claim need be described unless it departs from the normal kind of such actions.
2. No information need be given with respect to any proceeding that involves primarily a claim for damages if the amount involved, exclusive of interest and costs, does not exceed 10 percent of the current assets of the registrant and its subsidiaries on a consolidated basis. However, if any proceeding presents in large degree the same legal and factual issues as other proceedings pending or known to be contemplated, the amount involved in such other proceedings shall be included in computing such percentage.
3. Notwithstanding Instructions 1 and 2, any material bankruptcy, receivership, or similar proceeding with respect to the registrant or any of its significant subsidiaries shall be described.
4. Any material proceedings to which any director, officer or affiliate of the registrant, any owner of record or beneficially of more than five percent of any class of voting securities of the registrant, or any associate of any such director, officer, affiliate of the registrant, or security holder is a party adverse to the registrant or any of its subsidiaries or has a material interest adverse to the registrant or any of its subsidiaries also shall be described.
5. Notwithstanding the foregoing, an administrative or judicial proceeding (including, for purposes of A and B of this Instruction, proceedings which present in large degree the same issues) arising under any Federal, State or local provisions that have been enacted or adopted regulating the discharge of materials into the environment or primary for the purpose of protecting the environment shall not be deemed "ordinary routine litigation incidental to the business" and shall be described if:
 - A. Such proceeding is material to the business or financial condition of the registrant;
 - B. Such proceeding involves primarily a claim for damages, or involves potential monetary sanctions, capital expenditures, deferred charges or charges to income and the amount involved, exclusive of interest and costs, exceeds 10 percent of the current assets of the registrant and its subsidiaries on a consolidated basis; or
 - C. A governmental authority is a party to such proceeding and such proceeding involves potential monetary sanctions, unless the registrant reasonably believes that such proceeding will result in no monetary sanctions, or in monetary sanctions, exclusive of interest and costs, of less than \$100,000; provided, however, that such proceedings which are similar in nature may be grouped and described generically.